

REMARKS

Applicants respectfully request favorable reconsideration of this application.

The specification has been amended to address the objection to the drawings.

Claim 53 has been amended to address the objection.

Claims 1-6, 9-13, 19-20, 25-27, 32-33, 42-51, and 54-61 stand rejected under 35 U.S.C. §§ 101, 112 (first and second paragraphs) and 102(e).

Rejection under 101

The rejection under § 101 is respectfully traversed. Each of the independent claims is directed to statutory subject matter. For example, Claim 1 recites a method of detecting a loss of integrity in a blood circuit supplying blood to a patient, comprising the steps of detecting a leak of blood from an extracorporeal blood circuit in at least two independent ways to generate at least two leak detection signals, deriving at least one composite signal responsive to said two leak detection signals, and generating an alarm signal responsively to said at least one composite signal.

Applicants recognize that, according to the recent U.S. Supreme Court decision in the *Bilski* case, the machine or transformation test is not the *exclusive* test for patent eligibility. See, e.g., *Bilski et al. v. Kappos*, Slip Opinion, p. 7, No. 08-964, S. Ct., Decided June 28, 2010. Nevertheless, it is apparent that Claim 1, and the other independent claims, meet the transformation prong of the machine or transformation test as applied in the outstanding Office Action. In particular, the leak detection signals correspond to data representing a physical entity (e.g., a leak in an extracorporeal blood circuit). An exemplary list of signals can be found on pages 8-10 of the specification. The deriving of at least one composite signal is a transformation of the leak detection signals and the transformation is clearly central to the claimed method.

Moreover, the derivation of at least one composite signal is a transformation of data meeting the transformation test requirements set forth in the Interim Examination Instructions for Evaluating Patent Eligible Subject Matter Eligibility promulgated on August 24, 2009. For example, the derivation of a composite signal transforms data (e.g., signals) into a different state (e.g., into a composite signal capable of indicating a leak in an extracorporeal blood circuit). See, e.g., Interim Guidelines, pages 5 and 6.

Independent Claims 9, 13, 25, 42, 49, 50, 51 and 54 recite features similar to those discussed above regarding Claim 1. Moreover, independent Claims 9, 13, 42 and 54 are device claims and are not subject to the machine or transformation test as these independent claims, and their respective dependents, are not directed to a method or process. Further, Claims 9, 13, 42 and 54 are directed to a specific, practical application, namely, detection of a leak in an extracorporeal blood circuit. Regarding claims 9, 13, 42 and 54, Applicants respectfully submit that the specification discloses a device that can include a controller or a monitoring system node. See, e.g., specification pages 10 and 12, and FIG. 1B (ref. 350).

Accordingly, the rejection under § 101 is untenable and Applicants respectfully request that the rejection be withdrawn.

The rejections under § 112, first and second paragraphs, are respectfully traversed. The deriving and/or combining steps recited in the independent claims would be readily understood by one of ordinary skill in the art. Further, examples of computational techniques for deriving a composite signal or combining signals are disclosed on pages 9-12 of the specification. These examples, when combined with the figures and other teachings of the specification, are clearly sufficient to provide one of skill in the art with an enabling disclosure for implementing an embodiment of the invention to detect a leak in an extracorporeal blood circuit.

A controller or monitoring system would be programmed to perform claimed method steps, or components could be configured to implement an embodiment of a claimed device. The specification contains description of an algorithm, a number of possible input signals and a desired output result. From these items, one of ordinary skill in the art would readily recognize how to make an embodiment of the invention suitable for a contemplated use. It is not necessary to provide specific computer code or other implementation details, as these are typically different for each implementation and one of ordinary skill in the art would recognize that selection of the signals to combine or derive from is most likely tied to a particular extracorporeal blood circuit system, and a particular filtering or combining technique would be based on the signals being used and the signal characteristics thereof.

Applicants believe the specification, including written description and figures, sets forth a description sufficient for one of ordinary skill in the art to make and use an embodiment of the invention. Accordingly, Applicants respectfully request that the rejections under § 112, first and second paragraphs be withdrawn.

Rejection under 102(e)

The rejection under 102(e) is respectfully traversed. As mentioned above, independent Claim 1 recites a method of detecting a loss of integrity in a blood circuit supplying blood to a patient, comprising the steps of detecting a leak of blood from an extracorporeal blood circuit in at least two independent ways to generate at least two leak detection signals, deriving at least one composite signal responsive to said two leak detection signals, and generating an alarm signal responsively to said at least one composite signal. The other independent claims recite similar features.

While O'Mahoney mentions a leak detector (118) and an air detector (117). See, e.g., FIG. 1, and Col. 4, lines 34-37. O'Mahoney contains no teaching or suggestion of deriving at least one composite signal responsive to said two leak detection signals, as recited in Claim 1. O'Mahoney similarly fails to teach or suggest the features of independent Claims 9, 13, 25, 42, 49, 50, 51 and 54.

Accordingly, since independent Claims 1, 9, 13, 25, 42, 49, 50, 51 and 54 and their respective dependents contain features that are not found in the applied references, Applicants propose the rejection should be withdrawn.

Should the Examiner believe that any further action is necessary to place this application in better form for allowance, the Examiner is invited to contact Applicants' representative at the telephone number listed below.

The Commissioner is hereby authorized to charge to Deposit Account No. 50-1165 (T4342-14516US01) any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper and to credit any overpayment to that Account. If any extension of time is required in connection with the filing of this paper and has not been separately requested, such extension is hereby requested.

Respectfully submitted,

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By: /Stephen W. Aycock II/
Mark A. Catan
Reg. No. 38,720

Miles & Stockbridge, P.C.
1751 Pinnacle Drive
Suite 500
McLean, Virginia 22102-3833
(703) 903-9000

Stephen W. Aycock II
Reg. No. 52,579